

Remarks/Arguments:

Claims 8-9 and 11-30 are canceled without prejudice. Claims 1 and 34-35 are amended. Support for the amendments can be found, e.g., at page 16, lines 11 - page 30, line 23 of the specification. No new matter is introduced.

Claims 1-7, 10, and 31-35 are pending in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

CLAIM REJECTIONS UNDER 35 USC § 103(a)

Claims 31-33 remain rejected as being unpatentable over Palmieri et al. (Journal of Clinical Oncology 19(5):1437-1443; "Palmieri") in view of Scholl et al. (Cancer Research 61:823-826; "Scholl") and Kuo (Clinical Cancer Research 4:411-418; "Kuo"). Applicants respectfully traverse.

Claim 31 is directed to a method for detecting the expression of a panel of marker genes including GalNAcT or PAX3 in an SLN sample from a melanoma patient and histopathologically negative for melanoma cells. In contrast, Palmieri discloses detection of Tyrosinase and MART-1 in histopathologically negative SLN samples obtained from melanoma patients (see page 1437, left column, 1st paragraph, lines 7-12 and 2nd paragraph, lines 3-5). Scholl discloses detection of PAX3 in cultured primary melanomas and their corresponding tissue sections (see page 823, left column, Abstract, lines 5-11 and right column, last paragraph, lines 4-6). Kuo discloses detection of GalNAcT in melanoma cell lines, primary melanoma biopsies, histopathologically positive tumor-draining lymph node (TDLN) metastases, distal organ metastases, and blood (see page 413, right column, Table 1 and 1st paragraph following Table 1, lines 14-15; page 414, left column, Table 2). The Examiner agreed that none of the three references discloses detection of GalNAcT or PAX3 in histopathologically negative SLN samples (the Office Action, page 6, lines 12-13). Nevertheless, the Examiner believed that one skilled in the art would have been motivated to detect GalNAcT or PAX3 in histopathologically

negative SLN samples and would have done so with a reasonable expectation of success.

Applicants respectfully disagree with the Examiner. It is Applicants' discovery that GalNAcT and PAX3 are expressed in histopathologically negative SLN samples from melanoma patients. Without such knowledge, one skilled in the art would not have been motivated to use GalNAcT or PAX3 as a gene marker when analyzing histopathologically negative SLN samples from melanoma patients. Furthermore, since none of the three references discloses detection of GalNAcT or PAX3 in histopathologically negative SLN samples from melanoma patients, one skilled in the art would not have reasonably expected that the mRNA transcripts encoded by GalNAcT and PAX3 can be detected in histopathologically negative SLN samples from melanoma patients. Therefore, claim 31 is patentable over the cited art. Claims 32-33, dependant directly or indirectly from claim 31, are also patentable over the cited art for at least the same reasons. The rejections should be withdrawn.

DOUBLE PATENTING

Claims 1-7, 10, and 31-34 remain provisionally rejected on the ground of non-statutory obviousness-type double patenting over claims 1-16 of co-pending U.S. Patent Application No. 11/227,575. If the pending claims are found to be otherwise allowable except for this ground of rejection, Applicants will submit an appropriate terminal disclaimer. In this event, Applicants respectfully request that the Examiner telephone the undersigned who will then provide the terminal disclaimer.

New Rejections Necessitated by Amendments

CLAIM REJECTIONS UNDER 35 USC § 112, SECOND PARAGRAPH AND
CLAIM REJECTIONS UNDER 35 USC § 112, FIRST PARAGRAPH -
ENABLEMENT

Claims 1-7, 10, and 34-35 are rejected as being indefinite and for lack of enablement. Claims 1 and 34-35 are independent claims; claims 2-7 and 10 depend directly or indirectly from claim 1. The Examiner stated that it is not clear, in the rejected claims, what the probabilities are compared to. Without acquiescence in the Examiner's rejections, Applicants have amended claims 1 and 34-35, as suggested by the Examiner, to clarify that the comparisons are made relative to the probabilities of the second melanoma patient. Applicants respectfully submit that the rejections have been overcome and should be withdrawn.

CONCLUSION

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned at the Los Angeles, California telephone number (310) 785-4600 to discuss the steps necessary for placing the application in condition for allowance.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1314.

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Respectfully submitted,

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